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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,449	08/16/2006	Mariko Kuroda	P29911	8465

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EXAMINER	
ANDERSON, DENISE R	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
02/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/579,449	KURODA ET AL.	
	Examiner	Art Unit	
	Denise R. Anderson	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 6-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2009 has been entered.

Claim Objections

3. Applicant amended claim 6 and cancelled claims 11 and 12. The previous objections for minor informalities are withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, and 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 contains the trademark/trade name

polyvinylpyrrolidone K90. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polyvinylpyrrolidone and, accordingly, the identification/description is indefinite.

6. In the patentability analysis below, the examiner will interpret the claim limitation of "polyvinylpyrrolidone K 90" to mean polyvinylpyrrolidone of molecular weight of around 10,000 up to 800,000. The lower molecular weight figure is from the entry in the Cameo Chemicals (http://www.cameochemicals.noaa.gov/report/?chem_id=20942) database. Cameo Chemicals is an online database of hazardous materials maintained by the US government. In that database, polyvinylpyrrolidone is stated to have an alternate chemical name of "K 90" (p. 4, line 24) and an average molecular weight of 10,000 (p. 3, line 11). The higher molecular weight figure is from Wu et al. (US Patent No. 5,338,814, Aug. 16, 1994) that details a "Process for Making Narrow Molecular Weight Distribution Polyvinylpyrrolidone K-90 Polymers" with "molecular weight of 500,000 to 800,000." Wu et al, Title; Column 2, lines 40-43.

Claim Rejections - 35 USC § 103

7. Claims 1-2 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited), in view of Kozawa et al. (US Patent No. 6,355,730 B1, Mar. 12, 2002). Kozawa et al. discloses hollow fiber membranes formed from polysulfone-based resins and polyvinyl pyrrolidone for use in dialysis. Kozawa et al., Abstract, lines 1-8; Column 2, lines 48-52.

8. Kim et al. discloses a membrane that is "usable in blood dialysis, plasma separation, etc." Kim et al., Abstract, lines 1-6. Kim et al. further teaches a hollow fiber membrane spun from a solution of aromatic polysulfone, polyvinyl pyrrolidone, and N-methyl-2-pyrrolidone – and the measured zeta potential of the hollow fiber is -1 at pH 7.4, using a 0.001 mol/l potassium chloride solution. Kim et al., Comparative Example 1 at ¶ 195 and in Table 1; ¶ 159. Kozawa et al. discloses hollow fiber membranes formed from polysulfone-based resins and polyvinyl pyrrolidone for use in dialysis. Kozawa et al., Abstract, lines 1-8; Column 2, lines 48-52.

9. Independent claim 1 appears below in italics with the prior art and examiner's comments in normal font. The patentability analysis follows for dependant claims 2 and 6-7.

Claim 1. (Currently amended) A hollow fiber membrane (Kim et al., ¶ 195, line 17-18) *for blood purification* (Kim et al., Abstract, lines 1-6)

obtained by running a raw spinning solution comprising polysulfone-based resin, polyvinylpyrrolidone K90 (the examiner is interpreting this to mean a

molecular weight of around 10,000 up to 800,000 which Kim et al. teaches at ¶ 141 where it is stated that "polyvinyl pyrrolidone . . . has a weight average molecular weight of 5,000 or more, and preferably 8,000 or more"), *and dimethyl acetamide, through an air gap whose relative humidity is 75% to 90% for 0.4 seconds or more* (Kim et al., ¶ 195, lines 9-13 when Kim et al. teaches, "The extruded hollow fiber was caused to run through a hood saturated with water vapor at an average temperature of 40^{O}C, immersed in water at 55OC in a bath installed 600 mm below the spinneret, and wound around a bobbin at a rate of 50 m/min.").

having an integrally continuous structure (Kim et al., ¶ 195, the hollow fiber membrane was spun from a "homogeneous spinning solution" indicating an integrally continuous structure) *from the inner membrane surface to the outer membrane surface, the membrane comprising a hydrophobic polymer* (Kim et al., ¶ 195, lines 1-5, the hollow fiber membrane was spun from "aromatic polysulfone" which is a hydrophobic polymer) *and a hydrophilic polymer* (Kim et al., ¶ 195, lines 1-5, the hollow fiber membrane was spun from "polyvinyl pyrrolidone" which is a hydrophilic polymer), *having a polyvinylpyrrolidone concentration in the hollow fiber membrane of between 3.0 and 5.0 wt%* (Kozawa et al., Column 13, lines 63-33) *and*

exhibiting a zeta potential (Kim et al., Comparative Example 1 at ¶ 195 and in Table 1 where the measured zeta potential was -1 at a pH of 7.4; ¶ 158

where the zeta potential measurement was described and included using a 0.001 mole/l potassium chloride solution) *on the inner surface thereof of greater than -3.0 mV but less than 0 mV at pH 7.5, when measured using a sample with an embedded resin on the outer side for allowing the electrolyte solution to flow through only the inside of the hollow fiber, and using a 0.001 mol/l potassium chloride aqueous solution as an electrolyte solution.*

10. Kim et al. discloses the claimed invention except for the humidity in the air gap being saturated, instead of the recited 75% to 90%. Both Kim et al. (¶ 195, lines 9-13) and applicant run the hollow fiber from the spinneret through an air gap and then promptly introduce the hollow fiber into a water bath. In applicant's words the water bath is described as "a coagulation bath containing water as a main component installed below the spinneret." Specification, ¶ 76, lines 12-14. Given both processes use water baths, it would have been obvious to one of ordinary skill in the art to make the Kim et al. hollow fiber with 90% humidity in the air gap instead of 100% humidity since this is the simple substitution of one known element (100 % humidity) for another (90% humidity) to obtain predictable results (the hollow fiber is plunged into a water bath with high humidity at the water bath's interface and the hollow fiber is cooled through the water bath and wound around a bobbin).

11. Kim et al. discloses the claimed invention except for explicitly stating the polyvinyl pyrrolidone membrane content is 3.0% to 5.0%. Kozawa et al. teaches that the hollow fiber membranes have a polyvinyl pyrrolidone content "in an amount of 3 to 15% by

weight of the polysulfone," which encompasses the 3.0% to 5.0 wt. % range recited in claim 1. Kozawa et al., Column 13, lines 63-66. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the Kim et al. membrane to have a 3.0% to 5.0% pyrrolidone membrane content, as taught by Kozawa et al., since Kozawa et al. states in the Abstract, lines 2 and 5-6, that such a modification would produce a membrane material "usable in blood dialysis" and also "have an extremely high biocompatibility."

12. In summary, Kim et al., in view of Kozawa et al., discloses or suggests all claim 1 limitations.

13. With regards to the hollow fiber membrane properties recited in claims 2 and 6, Kim et al., in Table 1, further teaches an albumin sieving coefficient of 0.011 (1.1% versus the recited < 0.6%) and a protein adsorption amount of 4.2 mg/m^2 (versus the recited < 65 mg/m^2). Kim et al. also teaches that a "first object of the present invention" is to provide a hollow fiber membrane "that can separate a human serum albumin with a molecular weight of about 67,000 from proteins with a molecular weight in the range of 30,000-40,000." Kim et al., ¶ 19, lines 7-13; ¶ 6, lines 4-13. Thus, the Kim et al. hollow fiber membranes will remove more than 45% of a polyvinyl pyrrolidone with a weight average molecular weight of 40,000.

14. Kim fails to disclose the property limitations recited in claim 2, subparagraphs (d) and (e) which are the breaking strength and breaking elongation of the membrane. Kim also fails to disclose applicant's calculated – not measured – mass transfer coefficient

shown in the Specification, ¶ 49 that applicant recites must be "0.040 cm/min or greater" in claim 6. However, a membrane's properties are determined by its composition, and the polymer membrane of the reference has the same composition as the polymer membrane described by instant claims 1 and original claims 3 and 4. For these reasons, the cited properties are presumed to be inherent to the membrane of the reference. See MPEP 2112.

15. In summary, Kim et al., in view of Kozawa et al. discloses or suggests all limitations recited in claims 2 and 6.

16. Regarding claim 7, Kim et al. also teaches a dense layer thickness of 1 to 20 μm and this includes applicant's recited range of 1 to 5 μm in claim 7. Kim et al., ¶ 57, lines 5-7. In summary, Kim et al., in view of Kozawa et al., discloses or suggests all claim 7 limitations.

17. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO/2002/087735, Jul. 11, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited), in view of Kozawa et al. (US Patent No. 6,355,730 B1, Mar. 12, 2002) as applied to claim 1 above, and further in view of Carlsen et al. (US Patent No. Re. 36,914, Oct. 17, 2000). Carlsen et al. discloses a "dialysate filter" (applicant's blood purification apparatus) that has "an asymmetric microporous, hollow fiber membrane." Carlsen et al., Title, Figures 1 and 2.

18. With regards to claim 8, Carlsen et al., in Figure 2, discloses a cylindrical container with two nozzles (labeled "inlet port" and "outlet port") for flow dialysate.

Carlsen et al. further teaches a potting material to separate the hollow inside of the membrane from the outside of the membrane. Carlsen et al., Column 11, lines 30-32. Finally, in Figure 2, Carlsen et al. discloses a header cap at both ends of the apparatus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have installed the Kim et al. hollow fiber membranes into a blood purification apparatus, as taught by Carlsen et al., since Kim et al. states in the Abstract, lines 1-5 that the Kim et al. hollow fiber membranes are "usable in blood dialysis" and Carlsen et al states in the Title that the Carlsen et al. apparatus is a "dialysate filter" incorporating "hollow fiber membranes." In summary, Kim et al., in view of Carlsen et al., discloses or suggests all claim 8 limitations.

19. Regarding claim 9, Kim et al., in view of Carlsen et al., discloses the claimed invention except for explicitly stating that the phosphorus clearance is 180 ml/min for a 1.5 m^2 membrane area. Because the structure of the Kim et al. hollow fiber membrane is the same as that recited by applicant and structure governs phosphorous clearance, the Kim et al. hollow fiber membrane in the Carlsen apparatus would exhibit the phosphorous clearance of 180 ml/min for a 1.5 m^2 membrane area. Thus, Kim et al., in view of Carlsen et al., discloses or suggests all claim 9 limitations.

20. As an aside, Kozawa et al. (US Patent No. 6,355,730 B1, March 12, 2002) discloses a method to calculate both phosphorus clearance [claim 9] and overall mass transfer coefficients [claim 6] in the context of, "Membrane materials for removing uremic toxins from a hydrophobic polymer such as polysulfone and two polyvinyl

pyrrolidones, hydrophilic polymers of different molecular weights, that is 10-50 wt. % of a low molecular weight component (molecular weight < 100,000) and 90-50 wt. % of a high molecular weight component (molecular weight $\geq$ 100,000). The membranes are permselective useful in dialysis." Kozawa et al., Abstract, lines 1-8. Unfortunately, the Kozawa et al. clearance calculation was different from that of applicant and there is not enough data to put the two calculations on the same basis. Kozawa et al., Column 7, lines 49-66. Applicant's Specification, ¶¶ 49-55. Similarly, since the overall mass transfer calculation is based on the clearance calculation, there is not enough data to put applicant's calculation on the same basis with that of Kozawa et al.

21. Because calculations of phosphorus clearance and overall mass transfer coefficients are different between applicant and Kozawa et al., the examiner will continue to make the argument that the structure of the Kim et al. hollow fiber membrane is the same as that recited by applicant. Since the structure governs phosphorous clearance or the overall mass transfer coefficient, the Kim et al. hollow fiber membrane would exhibit the phosphorous clearance or overall mass transfer coefficient recited in the claim.

Response to Arguments

22. Applicant's arguments filed January 16, 2009 have been fully considered but they are not persuasive.

23. Applicant makes the following arguments. The examiner's response is presented after each argument.

a. Applicant argues, "In order to reduce protein adsorption amount to the hollow fiber membrane, it is desirable to set the polypyrrolidone concentration in the hollow fiber membrane in the range of 3.0 to 5.0 wt%. Applicants respectively submit that Kim et al. fails to disclose a membrane having these features and advantages." Applicant's Remarks, p. 4, lines 26-29.

The examiner will respond as in the above patentability analysis. Kim et al. discloses the claimed invention except for explicitly stating the polyvinyl pyrrolidone membrane content is 3.0% to 5.0%. Kozawa et al. teaches that the hollow fiber membranes have a polyvinyl pyrrolidone content "in an amount of 3 to 15% by weight of the polysulfone," which encompasses the 3.0% to 5.0 wt. % range recited in claim 1. Kozawa et al., Column 13, lines 63-66. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the Kim et al. membrane to have a 3.0% to 5.0% pyrrolidone membrane content, as taught by Kozawa et al., since Kozawa et al. states in the Abstract, lines 2 and 5-6, that such a modification would produce a membrane material "usable in blood dialysis" and also "have an extremely high biocompatibility."

b. Applicant argues, "Kim et al. does not disclose the molecular weight of the polyvinylpyrrolidone in comparative example 1." Applicant's Remarks, p. 5, lines 7-8. Furthermore, Kozawa et al. does not disclose this. Applicant's Remarks, p. 8, lines 4-5. The examiner will interpret this to mean that

applicant is claiming the molecular weight of the polyvinylpyrrolidone in claim 1 by reciting "polyvinylpyrrolidone K90."

The examiner will respond as in the above patentability analysis. Claims 1, 2, and 6-9 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because claim 1 contained the trademark/trade name polyvinylpyrrolidone K90. As was stated in the rejection, the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polyvinylpyrrolidone and, accordingly, the identification/description is indefinite.

In the patentability analysis above, the examiner interpreted the claim limitation of "polyvinylpyrrolidone K 90" to mean polyvinylpyrrolidone of molecular weight of around 10,000 up to 800,000. The lower molecular weight figure came from the entry in the Cameo Chemicals (http://www.cameochemicals.noaa.gov/report/?chem_id=20942) database. Cameo Chemicals is an online database of hazardous materials maintained by the US government. In that database, polyvinylpyrrolidone is stated to have an alternate chemical name of "K 90" (p. 4, line 24) and an average molecular weight of 10,000 (p. 3, line 11). The higher molecular weight figure

is from Wu et al. (US Patent No. 5,338,814, Aug. 16, 1994) that details a "Process for Making Narrow Molecular Weight Distribution Polyvinylpyrrolidone K-90 Polymers" with "molecular weight of 500,000 to 800,000." Wu et al, Title; Column 2, lines 40-43.

As was stated in the above patentability analysis, when "polyvinylpyrrolidone K 90" is interpreted to mean polyvinylpyrrolidone of molecular weight of around 10,000 up to 800,000, then Kim et al. teaches this at ¶ 141, lines 13-14 and 16-18 where it is stated that "polyvinyl pyrrolidone . . . has a weight average molecular weight of 5,000 or more, and preferably 8,000 or more."

c. Applicant argues, "[T]he zeta potential of the hollow fiber obtained in the present invention is different from that obtained by Kim et al." because "Kim et al. . . . discloses in comparative example 1 that the extruded hollow fiber was caused to run through a hood saturated with water vapor, which is believed to be greater than 95%, and which is outside the presently claimed range of humidity." Applicant's Remarks, p. 5, lines 22-23 and 17-20. Furthermore, Kozawa et al. does not disclose this. Applicant's Remarks, p. 8, lines 4-5.

The examiner will respond as in the above patentability analysis. Kim et al. discloses the claimed invention except for the humidity in the air gap being saturated, instead of the recited 75% to 90%. Both Kim et al. (¶ 195, lines 9-13) and applicant run the hollow fiber from the spinneret through an air gap

and then promptly introduce the hollow fiber into a water bath. In applicant's words the water bath is described as "a coagulation bath containing water as a main component installed below the spinneret." Specification, ¶ 76, lines 12-14. Given both processes use water baths, it would have been obvious to one of ordinary skill in the art to make the Kim et al. hollow fiber with 90% humidity in the air gap instead of 100% humidity since this is the simple substitution of one known element (100 % humidity) for another (90% humidity) to obtain predictable results (the hollow fiber is plunged into a water bath with high humidity at the water bath's interface and the hollow fiber is cooled through the water bath and wound around a bobbin).

d. Applicant argues, "The hollow fiber of Kim et al. cannot be deemed to have a zeta potential higher than -3.0 mV and less than 0 mV, as those values are tested in the present invention" because, "Kim et al. discloses in Table 1 in comparative example 1 that the zeta potential of the hollow fiber is -1 mV. . . . [T]his value is obtained by a different method than that used in the present specification: a method without using a sample with an embedded resin on the outer side for allowing the electrolyte solution to flow through only the inside of the hollow fiber." Applicant's Remarks, p. 5, line 31 to p. 6, line 2; p. 5, lines 25-29. Furthermore, Kozawa et al. does not disclose this. Applicant's Remarks, p. 8, lines 4-5.

This argument was addressed in the office action, dated August 28, 2008 and will be repeated here.

Applicant's arguments, filed June 16, 2008, stated that applicant had made the Example 1 polymer fiber of Kim et al. and had measured the zeta potential -- except for three changes. Those changes are listed below.

(1) Applicant substituted Kim's solvent of N-methyl-2-pyrrolidone for dimethyl acetamide in order to get the polyvinyl pyrrolidone into the recited range of 3.0% to 5.0% of dependent claim 5. Applicant's Response, June 16, 2008, p. 10, lines 4-8.

(2) The Kim et al. hollow fiber was made with "polyvinyl pyrrolidone of unknown molecular weight" and applicant did not state how this issue was handled experimentally. Applicant's Response, p. 9, Section entitled "Difference in Membrane Structure," lines 6-8.

(3) The zeta-potential was measured differently, i.e. the "zeta potential . . . was measured having an embedded resin on the outer side of the membrane" and, presumably, Kim et al. did not embed the fiber in resin. Applicant's Response, Section entitled Declaration under 37 C.F.R. 1.132, lines 2-4.

Applicant measured the zeta potential of this fiber to be +4.0 and not the -1.0 zeta potential shown by Kim et al. in Table 1, Comparative Example 1, last column. Applicant's Response, Section entitled Declaration under 37 C.F.R. 1.132, lines 2-4. The +4.0 zeta potential is outside applicant's claimed range

of -3.0 to 0.0 and applicant asserts that Kim et al. does not anticipate applicant's claimed hollow fiber membrane.

The examiner's response is that the one data point lacks at least a control and also a replicate. From the one data point, it is unknown how much each of the three changes, plus experimental error, contributed to the move from a -1.0 zeta potential to a +4.0 zeta potential. As such, the examiner maintains the claim 1 rejection where the zeta potential limitation is addressed.

To summarize the claim 1 patentability analysis regarding the zeta potential limitation, Kim et al. discloses a membrane that is "usable in blood dialysis, plasma separation, etc." Kim et al., Abstract, lines 1-6. Kim et al. further teaches a hollow fiber membrane spun from a solution of aromatic polysulfone, polyvinyl pyrrolidone, and N-methyl-2-pyrrolidone – and the measured zeta potential of the hollow fiber was -1 at pH 7.4, using a 0.001 mol/l potassium chloride solution. Kim et al., Comparative Example 1 at ¶ 195 and in Table 1; ¶ 159.

e. Applicant argues, "[T]he hollow fiber membrane of the present invention has a useful charge (zeta potential) on the inner surface. Applicants respectfully submit that this difference is not taught or suggested by Kim et al. or Kozawa et al." Applicant's Remarks, p. 8, lines 12-14.

There are three available responses to this argument. In response to applicant's argument that the references fail to show certain features of

applicant's invention, it is noted that the features upon which applicant relies (i.e., charge on the inner surface of the hollow fiber membrane) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Second, even if the limitation were recited, Kim et al. discloses in the Abstract, lines 6-12, "[p]orous films . . . having an asymmetric structure wherein . . . a dense layer substantially not charged . . . is provided in the side on which the liquid is to be treated" and the other side of the film "is negatively charged." Kim et al. further teaches, "The membrane may be either a flat membrane or a hollow fiber membrane with no specific limitations to the configuration inasmuch as this structure can be maintained." Kim et al., ¶ 56, lines 9-11. As such, Kim et al. discloses charge on the inner surface of the hollow fiber membrane when the fluid to be treated is loaded on the outside of the hollow fiber membrane.

Third, even if the limitation were recited and Kim et al. had remained silent on whether the charge was inside or outside the hollow fiber membrane, it would have been obvious to try this configuration since this is an example of choosing from a finite number (two) of identified (charge is on the inside of the hollow fiber, charge is on the outside of the hollow fiber), predictable solutions (filtrate is generated as the liquid to be treated crosses first the dense layer and then the charged layer).

f. Applicant argues, "[A] person of skill in the art would not modify the teachings of either of these cited references to arrive at applicant's claimed invention" because, "Neither Kim et al. nor Kozawa et al. seeks to provide a hollow fiber membrane or apparatus capable of the features of the presently claimed invention: enhanced phosphorus-removing performance without compromising antithrombogenecity." Applicant's Remarks, p. 7, lines 30-32; p. 7, lines 26-28.

In response to applicant's argument that the references do not explicitly teach the feature of enhanced phosphorus-removing performance without compromising antithrombogenecity, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

g. Applicant argues, "[T]here is no reason a person of ordinary skill in the art would combine the teachings of Kim et al. with those of Kozawa et al." because, "A person of ordinary skill in the art, seeking to make dialysis membranes, would not look beyond Kim et al.". The examiner will interpret this argument to be that Kozawa et al. is non-analogous art.

In response to applicant's argument that Kozawa et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Kozawa et al. et al. discloses "permselective membranes . . . used for blood treatment." As such, Kozawa et al. is in applicant's field of endeavor of hollow fiber membranes and the Kozawa et al. reference is reasonably pertinent to applicant's particular problem of blood purification.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise R. Anderson whose telephone number is (571)270-3166. The examiner can normally be reached on Monday through Thursday, from 8:00 am to 6:00 pm.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter D. Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DRA

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797